

## **REMARKS**

### **Status of the Claims**

Upon entry of the amendment, claims 13, 14, 17 and 18 are pending.

Claims 3, 7, 15 and 16 have been cancelled and claims 19-22 have been withdrawn, all without prejudice or disclaimer. Claims 13 and 14 have been amended. Support for these claims is found throughout the specification as filed, for example, at page 5, lines 15-16; page 9, line 14 to page 10, line 4, page 39, line 17 to page 42, line 18 and in the sequence listing. Therefore, this Amendment adds no new matter.

### **Summary of Examiner Interview and Comments**

Applicants would like to thank the Examiner for taking the time to discuss the Applicants' proposed claims. As discussed, Applicants have made the proposed amendments to the claims and have further incorporated the Examiner's suggestion to cancel claim 3 and rewrite claims 13 and 14 as independent claims.

The Examiner requested clarification as to the cytomegalovirus (CMV) strains and methods for strain identification commonly used in the art at the time of the invention. Detailed restriction enzyme maps, commonly used for strain identification and to characterize CMV genomes, were available for AD169 (see, *e.g.*, Figure 12, Spector et al, 1982, *J Virol* 42:558-82, attached as Exhibit A), Towne (see, *e.g.*, Figure 4, Pande et al, 1984, *PNAS* 54:817-24, attached as Exhibit B) and Toledo (see, *e.g.*, Figure 6, US Patent 5,721,354, attached as Exhibit C). In addition, Cha et al (1996, *J Virol* 70:78-83, attached as Exhibit D) describe the Towne and AD169 strains as "widely used in laboratory studies" (see, page 78, first paragraph left side) and discusses the use of Toledo in the clinic (see, page 78, second paragraph right side). Together, these references clearly indicate that these strains were well known, easily identified and readily available as early as 1982.

Applicants have also provided, as requested by the Examiner, several references (Exhibits D-H) which will further support the use the nucleotide numbering convention of the AD169 genome for comparing the genomes of different CMV strains (also, see specification at, for example, page 9, line 14 to page 10, line 4 and page 41 lines 18-25). The use of the numbering convention of the AD169 genome is discussed in more detail below.

### **Rejection of Claims 13, 14, 17 and 18 Under 35 U.S.C. § 112, First Paragraph**

Claims 13, 14, 17 and 18 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

In particular, the Examiner has asserted that only polynucleotides of Chimera I were in the Applicant's possession at the time of the invention (see, *e.g.*, Office Action, page 5, third paragraph). Applicants respectfully disagree and traverse and point out that Applicants were in possession of numerous other polynucleotides at the time of the invention including Chimeras II, III, IV, Towne/Toll (see specification at, *e.g.*, page 41, line 15 to page 43, line 21) as well as certain other recombinant CMV genomes such as those disclosed, for example, on page 38, lines 1-21 of the instant specification.

In addition, the Examiner has asserted that the instant specification does not provide adequate written description of the claimed genus of a CMV construct comprising polynucleotides having at least 90% sequence identity with a particular disclosed sequence (see, *e.g.*, Office Action, page 4, first and second paragraphs).

Applicants respectfully disagree. However, at this time, solely in order to expedite prosecution, Applicants have amended independent claims 13 and 14 to remove the recitation "at least 90% identical to." Accordingly, reconsideration and withdrawal of the rejection of independent claims 13-14 and dependent claims 17-18 is respectfully requested.

### **Rejection of Claims 3, 7 and 13-18 Under 35 U.S.C. § 112, Second Paragraph**

Claims 3, 7 and 13-18 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

In particular, the Examiner asserts that the claims are drawn to a Chimera for which no sequences have been provided with which to reference the claimed nucleotides (see, *e.g.*, Office Action, page 6, second paragraph).

Applicants respectfully disagree. However, at this time, solely in order to expedite prosecution, Applicants have amended independent claim 14 to recite the SEQ ID NOS corresponding to the crossover regions of Chimera I. In addition, independent claims 13 and 14 have been amended to recite "wherein the nucleotide number of the Towne and Toledo genomes is according to the numbering convention of the AD169 genome."

Applicants respectfully point out that the identity of the claimed nucleotides can be readily determined by one of skill in the art by reference to the nucleotide numbering

convention of the commonly used reference strain, AD169. The sequence of the AD169 genome was known well known in the art (see, Chee et al., 1990, *Curr Top Microbiol Immunol*. 154, 125-169, attached as Exhibit E) and publicly available from GenBank (Acc. No. X17403). The numbering convention of the AD169 genome was commonly used for the identification, mapping and comparison of genomic regions of other CMV strains. Applicants have provided references that utilize the nucleotide numbering convention of the AD169 genome in studies of the Towne and/or Toledo CMV strains.

- Cha et al. (1995, *J Virol* 70:78-83, attached as Exhibit D) utilized the numbering convention of the AD169 genome for mapping studies of the Towne and Toledo genomes (see, *e.g.*, page 80 second paragraph, left side, Table 1 and Figures 1 and 2).
- Mocarski et al. (1996, *PNAS* 93:11321-11326, attached as Exhibit F) utilized the numbering convention of the AD169 genome in studies characterizing certain mutations of the IE1 gene in Towne and recombinant CMV strains (see, *e.g.*, Figure 1).
- Cihlar et al. (1998, *J Virol* 72:5927-36, attached as Exhibit G) utilized the numbering convention of the AD169 genome in studies of drug resistance mutations generated in Towne (see, *e.g.*, page 5928 second paragraph, right side and Figure 2).
- Haberland et al. (1999, *J Gen Virol* 80:1495-1500, attached as Exhibit H) utilized numbering convention of the AD169 genome for mapping variation with the gB gene of CMV clinical isolates (see, *e.g.*, Figure 1, 2 and 4).

The use of the numbering convention of the AD169 genome is also taught and utilized in the instant specification (see, *e.g.*, page 9, line 14 to page 10, line 4; page 14, lines 16-20 and page 41 lines 18-25). Thus, given the state of the art at the time of the invention it would be readily apparent, to one of skill in the art, exactly which nucleotides of Towne and Toledo are indicated in the currently amended claims by the recitation of particular numbered nucleotides which utilize the nucleotide numbering convention of the AD169 genome.

The Examiner has also asserted that the claims drawn to chimeric CMVs that have 90% identity are seemingly in conflict with the fixed sequences of the Chimera of claims 3 and 7 (see, *e.g.*, Office Action, page 6, third paragraph).

Applicants respectfully disagree, however, Applicants respectfully point out that claims 3, 7, 15 and 16 have been canceled and, as discussed above, independent claims 13 and 14 have been amended remove the recitation “at least 90% identical to.”

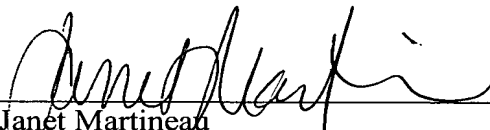
Lastly, the Examiner has asserted that the term "a high passage Towne genome" is unclear because the term is subject to individual interpretation (see, *e.g.*, Office Action, page 6, fourth paragraph).

Applicants respectfully disagree, however, at this time, solely in order to expedite prosecution, Applicants have amended independent claims 13 and 14 to recite "wherein the high-passage Towne genome has been passaged at least 50 times." Support for this amendment may be found, for example, at page 5, lines 15-16. In view of the foregoing, reconsideration and withdrawal of the rejection of independent claims 13-14 and dependent claims 17-18 is respectfully requested.

### **Conclusion**

In view of the above remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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